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09/763,957	06/18/2001	Rose Ramon Botella Mesa	229752001300	3466

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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 06/17/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,957

Applicant(s)

BOTELLA MESA ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7,9-15 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,7,9,10,15 and 19-25 is/are rejected.
- 7) ☒ Claim(s) 11-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This office action is in response to an amendment filed 4/4/03. Claims 2-4, 6, 8 and 16-18 are cancelled. Claims 1, 5, 7, 9-15, 19-25 are pending in this application.

Response to Amendment

The new title reading "A Plant Promoter and Uses Therefor." Is acknowledged and accepted.

The substitute specification is acknowledged and has been entered.

Objection to the disclosure due to references to their identifying <400> numeric indicators has been withdrawn as sequences and references to sequences are listed by SEQ ID NO: identifiers.

Objections to Figure 1 and 4 due to sequences disclosed in them that do not have SEQ ID Nos. associated with them is withdrawn as sequence identifiers have been added.

Objection to the disclosure as containing an embedded hyperlink and/or other form of browser-executable code on page 15 is withdrawn in light of deletion of the hyperlink.

Receipt of Formal drawings is acknowledged.

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Claim rejections under USC 102(b) as being anticipated by Rider et al. is withdrawn in light of amendment to claims.

Objection to claim 5 and 18-21 are objected to under 37 CFR 1.75(c) as being in improper form should refer to other claims in the alternative only and because a multiple dependent claim cannot depend from any other multiple dependent claim has been withdrawn in light of cancellation of claim 2-4 and claim 18 and in light of amendment to claim 19.

Objections to claims 4, 6, 7, 8, 9, 10 and 17 because sequences are listed with references to identifying <400> numeric indicators has been withdrawn in light of cancellation of claim 4, 6, 8 and 17 and in light of amendment to remaining claims that list sequences by their SEQ ID NO:.

Rejection to claim 1 under 35 U.S.C. 102(b) as being anticipated by Resnick et al. has been withdrawn in light of amendment to claim 1 to refer to a promoter that in its native form directs expression of ACC synthase.

Rejection to claims 1-2 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Blume et al. have been withdrawn in light of amendment to claim 1 to refer to a promoter that in its native form directs expression of ACC synthase, cancellation of claim 2 and amendment to claim 15 to read on a modular promoter with at least one portion derived from SEQ ID 3.

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Rejection to claims 2, 4, 6, 7, 15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite have been withdrawn in light of cancellation of claims 2, 4, 6 and 17 and amendment to claims 7 and 15.

Rejection to claims 2-3 under 35 U.S.C. 102(b) as being anticipated by Goodman et al. have been withdrawn in light of cancellation of claims 2-3.

Rejection to claims 1-4, 6-8, 10 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, has been withdrawn in light of amendment to claims in which language referring to derivatives and homologues and to promoter that have 25-50% similarity has been removed.

Specification

The disclosure is objected to because of the following informalities: In the substitute specification, incorrect symbols have been inserted to represent temperature (for example on page 16, 26, 32, 35, 39, 42- 45, 47-48, 59) and micro (for example page 28, 34, 35, 42- 47, 58) and for +/- (page 42, 43). Appropriate correction is required.

Claim Objections

Claims 11-14 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from a multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 11-14 not been further treated on the merits.

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Claim 9 is objected to because of the following informalities: "4" is inserted between the word primer and SEQ ID NO:4. Appropriate correction is required.

Claims 1 and 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Goodman et al. (WO 98/08449). Claim 19 recites a transgenic plant comprising a nucleic acid according to claims 1 and 22 and 24. This claim was previously objected to as a multiply dependent claim that depended from a multiple dependent claim and was therefore not treated on its merits. Goodman et al teach that the ACC synthase promoter is fused to GUS coding sequences, which are then used to generate transgenic plants of undisclosed origins (page 30, line 27 through page 31, line 15). **This rejection is maintained for reasons of record in the office action filed 6/18/2001, Paper No. 13.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 5, 10, 15 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is unclear in reciting that the isolated nucleic acid comprises the nucleotide sequence as set forth in SEQ ID NO; 2 as this sequence is an amino acid sequence. **This rejection is necessitated by amendment.**

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The term "substantially" in claim 10 is a relative term that renders the claim indefinite.

This rejection is maintained for reasons of record in the office action filed 10/4/02, Paper No. 9.

Claim 15 is vague for reciting a promoter derived from a promoter as set forth in SEQ ID NO:3. It is unclear how closely related the derived sequences are to the original sequences and it is also unclear what procedures were used to derive the claimed sequences. The metes and bounds of the claimed subject are unclear.

Claims 1, 5, 7, 9-10, 15, 19-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants claim a genus of promoters that includes promoters from any ACC synthase gene from any organism wherein the promoter is inducible in response to stress (claim 1). Applicants claim a genus of promoters that hybridize under low stringency conditions (6X SSC, 0.1% w/v SDS and 42C) (claim 3, 15 and 23). Applicant further claims a genus of promoters that are isolated by identifying a region on the genomic DNA which hybridizes to a primer corresponding to all or part of SEQ ID NO: 1 (claim 7).

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed

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correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. In the disclosure, applicants disclose that the ACC synthase from mung bean exemplifies the instantly claimed promoter. As an essential element, the promoter must be inducible in response to physical stimulation. The structure of a species is disclosed as the specification discloses the mung bean ACC synthase promoter and uses only this promoter in the examples to generate deletions. Given the diversity of ACC synthase genes claimed and the inability to determine which of these genes will also contain the essential element that the promoter of said gene is inducible by physical stimulation, it is concluded that each member of the claimed genus must be empirically determined. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of the claimed genus.

By claiming sequences hybridizing under low stringency conditions (6X SSC, 0.1% w/v SDS and 42°C), the relationship between the structure of the sequence and its function becomes unclear. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus. In the instant case, applicants only disclose a single inducible promoter that drives expression of ACC synthase and a modular promoter in which at least a part is responsible for driving expression of ACC synthase. Given the diversity of sequences that are should be identified following hybridization in 6XSSC, 0.1% w/v SDS and 42°C to SEQ ID NO:3 and the uncertainty that any such sequence will be effective at driving gene expression of a given gene, it must be considered that any promoter derivative or homologue must be

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empirically determined. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of the claimed genus.

By claiming sequences upstream of a region, which hybridizes to a primer corresponding to all or part of SEQ ID NO:1, the relationship between the structure of the sequence and its function becomes unclear. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus. In the instant case, applicants only disclose the inducible promoter that drives expression of ACC synthase. Given the diversity of sequences that correspond to all or part of SEQ ID NO:1 (which can be as small as one nucleotide) and the uncertainty that a sequence upstream of this region will be effective at driving gene expression of a given gene, it must be considered that any promoter must be empirically determined. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of the claimed genus. **This rejection is necessitated by amendment.**

Response to Amendment

Applicants traverse the claim rejections under 35 U.S.C 102(b) on page 6 of the amendment filed 4/4/03, Paper No. 13. Applicants argue that the invention of Goodman et al., while reading on a promoter which in its native form directs synthesis of a gene encoding 1-aminocyclopropanes-1-carboxylic acid (ACC) synthase, does not read on said promoter that is inducible to physical stimulation.

Applicant's arguments filed 3/25/03 have been fully considered but they are not persuasive. Goodman et al. teach a promoter driving expression of the ethylene production gene, ACC (aminocyclopropane-1-carboxylate) synthase (page 2, line 7-10). While this promoter drives transcription in response to ethylene or an equivalent compound (page 8, line 4-7), this does not exclude its induction by physical stimuli. Applicants themselves have admitted that the promoter that directs expression of the ACC synthase gene is inducible in its native form by physical stimuli (page 11, line 3-6). Since Goodman et al teaches a nucleic acid molecule defining a promoter that in its native form directs expression of ACC synthase, it must be concluded that absent evidence to the contrary, the promoter isolated according to the teachings of Goodman et al. should be inducible by physical stimulation.

Claims 1, 5, 7, 9, 10, 15 and 19-25 are rejected.

Claims 11-14 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from a multiple dependent claim.

Claim 9 is objected to for minor formalities.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kay Pinkney, whose telephone number is (703) 305-3553.

Maria B Marvich, PhD
Examiner
Art Unit 1636

June 16, 2003


DAVID GUZO
PRIMARY EXAMINER